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Board Mission
The Arizona State Board of Pharmacy protects the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications and devices and nonprescription medications.

The Board accomplishes its mission by:
♦ Issuing licenses to pharmacists, pharmacy interns, and pharmacy technicians;
♦ Issuing permits to pharmacies, manufacturers, wholesalers, and distributors;
♦ Conducting compliance inspections of permitted facilities;
♦ Investigating complaints and adjudicating violations of applicable state and federal laws and rules; and
♦ Promulgating and reviewing state rules and regulations.

Renewal Time for Your License/Permit
It may be renewal time for your license. Verify the expiration date on your license. If the expiration date is October 31, 2015, you will need to renew. Details pertaining to the renewal process are posted on the Board website, https://pharmacy.az.gov.

Patient Consultation
The last line of defense to ensure that the right medication is dispensed to the right patient is to perform that final discussion (consultation). Referencing R4-23-402, oral consultation is required whenever the following occurs:
1. The prescription medication has not been previously dispensed to the patient in the same strength or dosage form or with the same directions;
2. The pharmacist, through the exercise of professional judgment, determines that oral consultation is warranted; or
3. The patient or patient’s caregiver requests oral consultation.

Some key points that may be discussed include:
1. The medication’s trade name, generic name, common synonym, or other descriptive name(s) and, when appropriate, its therapeutic class and efficacy.
2. The medication’s use and expected benefits and action. This may include whether the medication is intended to cure a disease, eliminate or reduce symptoms, arrest or slow the disease process, or prevent the disease or a symptom.
3. The medication’s expected onset of action and what to do if the action does not occur.
4. The medication’s route, dosage form, dosage, and administration schedule (including duration of therapy).
5. Directions for preparing and using or administering the medication. This may include adaptation to fit the patient’s lifestyle or work environment.
6. Action to be taken in case of a missed dose.
7. Precautions to be observed during the medication’s use or administration, and the medication’s potential risks in relation to benefits. For injectable medications and administration devices, concern about latex allergy may be discussed.
8. Potential common and severe adverse effects that may occur, actions to prevent or minimize their occurrence, and actions to take if they occur, including notifying the prescriber, pharmacist, or other health care provider.
10. Potential drug-drug (including nonprescription), drug-food, and drug-disease interactions or contraindications.
12. Proper storage of the medication.
13. Proper disposal of contaminated or discontinued medications and used administration devices.

Continuing Education
The profession of pharmacy continues to evolve and has become a vital part of the health care system. Pharmacists continue to be the most accessible health care professionals and are the first line for patients’ better health. Having this responsibility, the information shared must be current and accurate.

R4-23-204. Continuing Education Requirements
A. General. In accordance with A.R.S. § 32-1925(G), the Board shall not renew a license unless the applicant has, during the two years preceding the application for renewal, participated in 30 contact hours (3.0 CEU’s) of continuing education activity sponsored by an Approved Provider as defined in
FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person’s ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.
Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that “injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.” More information about this recall is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.
R4-23-110, of which at least three contact hours (0.3 CEU’s) are approved courses in pharmacy law. Subject to A.R.S. § 32-1937, a pharmacist licensed for less than 24 months shall obtain continuing education units in an amount determined by multiplying 1.25 hours times the number of months between the date of initial licensure and the next license renewal date.

B. Acceptance of continuing education units (CEU’s). The Board shall:

1. Only accept CEU’s for continuing education activities sponsored by an Approved Provider;
2. Only accept CEU’s accrued during the two-year period immediately before licensure renewal;
3. Not allow CEU’s accrued in a biennial renewal period in excess of the 3.0 CEU’s required to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacist who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider to receive CEU’s for a presentation by following the same attendance procedures as any other attendant of the continuing education activity; and
5. Not accept as CEU’s the performance of normal teaching duties within a learning institution by a pharmacist whose primary responsibility is the education of health professionals.

C. Continuing education records and reporting CEU’s. A pharmacist shall:

1. Maintain continuing education records that:
   a. Verify the continuing education activities the pharmacist participated in during the preceding five years; and
   b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
2. At the time of licensure renewal, attest to the number of CEU’s the pharmacist participated in during the renewal period on the biennial renewal form; and
3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.

D. The Board may revoke, suspend, or place on probation the license of a pharmacist who fails to comply with continuing education participation, recording, or reporting requirements of this Section.

E. A pharmacist who is aggrieved by any decision of the Board or its administrative staff concerning continuing education units may request a hearing before the Board.

Compliance FAQs

Q: Schedule II – Changes: Can the pharmacist change the date-to-fill after talking to the prescribing doctor on a Schedule II prescription?

A: The date-to-fill is part of the directions written on the prescription; therefore, it would be allowed to change after speaking with the prescribing doctor.

Q: Schedule II – Changes: What changes can a pharmacist make to a Schedule II prescription after speaking to the prescriber over the phone?

A: A pharmacist can change the drug strength, dosage form, drug quantity, and the directions. Changes that cannot be made are the patient’s name, controlled substance (CS) prescribed, and the addition of a prescriber’s signature (prescription must be hand signed).

Q: Schedule II – Destruction: How are outdated Schedule II drugs destroyed?

A: Reverse distributor, Drug Enforcement Administration (DEA), or a Board-approved plan (on a case-by-case basis if approval is granted).

Q: Schedule II – Disposal: When a prescriber writes a new prescription for a CS but requires the destruction of a previously prescribed CS prior to the new medication being dispensed, how does a pharmacist go about fulfilling the prescriber’s request?

A: A pharmacist cannot accept the return of a CS except in a long-term care facility (LTCF). A pharmacist can witness the patient destroying the medication (eg, flushing down a toilet) and document that the medication was destroyed prior to the new medication being dispensed.

Q: Schedule II – Emergency: If a LTCF calls in an emergency 72-hour supply for a Schedule II, can that count as a hard copy?

A: No. A prescription must be mailed or faxed (Schedule II fax exceptions) within seven days and must have “Authorization for Emergency Dispensing” written across its face.

Q: Schedule II – General: Is it required to write the patient address on the hard copy for a CS if the information is contained on the label and retrievable in the computer database?

A: A label attached to the hard copy that contains the information fulfills the requirement.

Q: Schedule II – General: Is a pharmacist’s signature required on Schedule II hard copies, or will initials suffice?

A: It is acceptable to either sign, initial, or utilize an electronic record identifying the verifying pharmacist.

Q: Schedule II – General: Does a pharmacist need to cancel a Schedule II prescription across its face and sign?

A: No.

Q: Schedule II – General: Is it legal to write/fill a Schedule II prescription on the same page as a second prescription?

A: No, there can only be one Schedule II written on a prescription blank.

Q: Schedule II – General: Does post-dating a prescription for a Schedule II medication by the prescriber void the prescription?

A: In order to be valid, the prescription must have the date the prescriber wrote the prescription on the prescription. For more information, call the DEA office.

Q: Schedule II – General: Is a typed Schedule II prescription with an electronically signed signature a valid prescription?

A: No, the prescription needs to be hand signed by the prescriber.

Q: Schedule II – General: What does the law say about prescribers writing for controlled drugs for family members?

A: It is prohibited for doctors to prescribe narcotics for family members. Refer to the Arizona Medical Board for details.

Q: Schedule II – General: When a pharmacy has a change in pharmacist-in-charge (PIC) and is required to do a Schedule II-V inventory, can the PIC make it the annual inventory as well?

A: Yes, but the next Schedule II-V inventory must be within 365 days.

Q: Schedule II – General: Does a residential care facility need to report the disposal of CS that were prescribed for residents to DEA or the Board office?

A: No.

Q: Schedule II – Partial Fills: In which cases are partial fills on Schedule II prescriptions allowed?

A: Partial fills are allowed on Schedule II prescriptions when: 1) the pharmacist is unable to fill the entire amount and the remaining balance is dispersed within 72 hours, or 2) patients are residing in a LTCF/community-based care facility or diagnosed with a terminal illness in which prescriptions are good for 60 days from the date the prescription was written.

Q: Schedule II – Transfers: Can a Schedule II medication be transferred between pharmacies with interactive databases (eg, Walgreens)?

A: Under no circumstances can a Schedule II medication be transferred.
Q: Schedule II–V – General: What is the law for dispensing a CS for office use (Schedule II and Schedule III–V)?
A: A blanket prescription cannot be written to provide a medical office medications for administration. If the office requires Schedule II medications, a DEA Form 222 must be used to transfer the Schedule II stock. For all other medications, an invoice must be utilized.

Q: Schedule III–IV – General: How many refills are allowed by law on Schedule III–IV medications?
A: A prescription written for a Schedule III–IV medication is good for 6 months or 5 refills, whichever comes first.

Q: Schedule III–IV – General: Does the six-month limit for refills on a Schedule III–IV medication mean a six-month quantity limit?
A: No, the prescription is valid for six months after the date it is written and can have up to 5 refills. After six months, the prescription is no longer valid and any unused refills are void. The rules do not apply to quantity dispensed. (It is legal to dispense a prescribed quantity that exceeds a six-month supply.)

Q: Schedule III–V – Refills: Does a partial fill on a Schedule III–V medication constitute a refill?
A: Partial fills are allowed on Schedule III–V medications and do not constitute a refill. The partial dispensing may not exceed the total amount authorized in the prescription order.

Q: Schedule III–V – Refills: Can a patient request more than one refill at once on a Schedule III–V medication?
A: Schedule III–V medications must be filled in proper context; it is appropriate to contact the prescriber to authorize the request.

Q: Prescriptions – General: Can non-veterinarians write prescriptions for animals?
A: No, non-veterinarians writing prescriptions for animals is beyond their scope of practice.

Q: Prescriptions – Refills: If a prescriber dies or retires and surrenders his or her licenses, are prescription refills still valid?
A: Since there is no longer a patient-provider relationship, the refills become invalid. A one-time refill is acceptable to allow the patient time to find a new care provider.

Disciplinary Actions and Updates – Other Health Boards
Arizona Medical Board
Manuel Abrante, MD #22262 – Order for Surrender of License and Consent to the Same. Respondent ordered to immediately surrender his license for the practice of allopathic medicine in the state of Arizona and return his certificate of licensure to the Board. Effective June 4, 2015.

Mark R. Austein, MD #14196 – Interim Consent Agreement for Practice Limitation and Assessment (Non-Disciplinary). Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and demonstrates his ability to safely carry out approved health care tasks and receives the Board’s permission to do so. Effective July 27, 2015.

Robert J. Mondschein, MD #32344 – Interim Consent Agreement for Practice Restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Effective March 24, 2015.

George H. Yard, MD #3387 – Order for Surrender of License and Consent to the Same (Non-Disciplinary Suspend). Respondent ordered to immediately surrender his license for the practice of allopathic medicine in the state of Arizona and return his certificate of licensure to the Board. Effective June 4, 2015.

The Arizona State Board of Pharmacy News is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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